

Escalation Design

WHITE PAPER

Building the Issue-Escalation Nervous System That Catches Problems Early

Abstract

For every adverse event that actually occurs in a complex system, research suggests there are somewhere between three and three hundred near misses that preceded it, smaller signals that, if caught and acted on, could have prevented the larger failure. Healthcare's own safety reporting data shows how badly that opportunity gets missed in practice: near-miss events should make up roughly forty-four percent of total safety reports, but they actually account for just eleven percent, and nearly half of all reporting facilities have never logged a single near-miss. Clinical trial programs show the same pattern at the portfolio level. Phase II terminations climbed to thirty-one percent in 2025, up from twenty-nine percent two years earlier, and fifty-five percent of sites now take longer than five months to activate, outcomes that a well-designed escalation process often sees coming well before they become a formal statistic. This white paper applies established program governance best practices to designing the escalation pathways that catch small problems while they are still small, before they compound into the kind of finding a steering committee has to explain after the fact.

The Problem Nobody Escalated in Time

Almost every serious program failure has a quieter history behind it. Someone noticed something was off weeks or months before the formal incident, but the observation never made it to anyone with the authority or context to act on it. It stayed a private worry, a comment in a hallway conversation, or a line item buried in a status report nobody read closely. The failure that eventually surfaced was rarely a surprise to everyone involved. It was a surprise to leadership, because the escalation path that should have carried the early warning simply did not exist, or existed on paper without actually functioning.

Healthcare's own safety data quantifies how large this gap tends to be. For every adverse event that actually occurs, research points to somewhere between three and three hundred near misses that preceded it, the exact kind of early signal a functioning escalation system is built to catch.¹ Yet actual reporting badly undercounts these signals: near-miss events should represent roughly forty-four percent of total safety reports in a well-functioning system, but they account for only about eleven percent of what actually gets reported, and forty-five percent of facilities tracked in one national safety database have never logged a single near-miss event at all.² The gap is not a lack of near misses happening. It is a lack of anyone capturing and escalating them before they become something worse.

Clinical trial portfolios show a parallel pattern in program-level outcomes. Phase II trial terminations rose to thirty-one percent in 2025, up from twenty-nine percent in 2023 and roughly ten percentage points above pre-pandemic levels, with participant dropout and engagement failure now consuming program capital at a scale that goes well beyond inconvenience.³ Fifty-five percent of sites took longer than five months to activate in 2025, and sixty-six percent of sites reported frequent contract and budget delays, the kind of accumulating friction that, left unescalated, quietly erodes a program's timeline long before anyone declares a formal delay.⁴

Why Most Escalation Paths Exist on Paper Only

Most organizations already have something called an escalation process, usually documented in a governance charter or a risk management plan. The reason it fails to function in practice is rarely that it was poorly written. It is that the process was designed around the assumption that people will escalate rationally, weighing severity against political cost and deciding the issue is worth raising. That assumption ignores the very real, very human calculation happening underneath: raising an issue too early risks looking alarmist, raising it too late risks looking negligent, and the safest individual choice, in the moment, is often to wait and see if it resolves on its own.

That calculation repeats itself at every level of a program, compounding the delay each time. A site coordinator who notices a pattern waits to see if it recurs before mentioning it to a CRA. The CRA waits to see if the pattern holds across more than one site before flagging it to the program manager. The program manager waits for a second data point before raising it to the steering committee. Every individual delay is locally reasonable. The cumulative effect is a near miss that took weeks to travel a path that should have taken days, precisely the dynamic behind healthcare's own near-miss underreporting numbers.



Applying Best Practices: Designing an Escalation System That Actually Works

A foundational best practice in PMO governance identifies Governance and Decision Rights as a core maturity dimension, and escalation design is where that dimension either functions as a genuine early warning system or exists only as an unused diagram in a governance binder. Applying that discipline to a working escalation design means addressing the human incentives that block escalation, not just documenting the reporting lines. Four elements make up that design.

1. **Escalation Thresholds Defined in Advance, Not Judged in the Moment.** Specific, pre-agreed triggers, a defined variance, a repeated pattern, a missed date, remove the individual judgment call about whether something is worth raising, replacing it with a threshold that was already decided before anyone had a personal stake in the answer.
2. **A Low-Cost First Step.** The first rung of the escalation ladder should be genuinely low-stakes, a quick flag that does not require building a full business case or committing to a formal position, mirroring how the best near-miss reporting systems succeed by making the initial report fast and blame-free rather than treating every report as a formal incident.
3. **Explicit Protection Against Escalation Penalty.** The person who raises an issue that turns out to be a false alarm needs to see, concretely, that they are not penalized for raising it, or the organization trains its own people to stay quiet exactly as the near-miss underreporting data suggests happens by default.¹
4. **A Defined Response Time at Every Level.** Every point in the escalation path has a committed response window, not just an obligation to escalate, so the person raising an issue knows it will actually be addressed rather than disappearing into an inbox, which is often the real reason people stop bothering to raise things at all.

None of this requires a new technology platform or a large governance overhaul. It requires designing the escalation path around how people actually behave under uncertainty and reputational risk, rather than around how a governance chart assumes they will behave.

What Escalation Design Buys, and Where It Gets Hard

Advantages

- **Problems caught while they are still small:** A functioning early-rung escalation path catches the kind of pattern that, left to compound, becomes the site delay or termination showing up in industry-wide statistics.
- **Better organizational learning:** A system that actually captures near misses, not just full incidents, gives an organization far more data to learn from than one that only sees the failures large enough to force attention.
- **Reduced burden on senior leadership:** Well-designed thresholds mean senior leaders see genuinely significant issues, not a flood of noise, because the lower rungs of the ladder are actually absorbing and resolving what belongs there.
- **Higher trust in the process over time:** Once people see that raising a concern gets a timely response and does not carry a reputational cost, escalation becomes a habit rather than a last resort, compounding the system's effectiveness.



Risks and Barriers

- **Threshold calibration:** Triggers set too sensitively flood the system with noise and train people to ignore alerts; set too conservatively, they miss exactly the early signals the design is meant to catch. Getting this right takes iteration, not a single policy document.
 - **Leadership response discipline:** A defined response window only works if leadership actually honors it consistently. A commitment that gets missed even occasionally teaches people the escalation path is not reliable.
 - **Cultural residue from a blame-oriented past:** An organization with a history of penalizing bad news will need sustained, visible proof that the new system is different before behavior actually changes, not just a policy announcement.
 - **Escalation fatigue:** Even a well-designed system can be overused if thresholds are miscalibrated or if people begin escalating defensively to protect themselves rather than to genuinely flag risk, which requires active monitoring to catch and correct.
-

Case in Point: The Enrollment Pattern Three People Saw and Nobody Raised

A mid-size sponsor running a multi-site Phase II oncology trial had three separate CRAs independently notice, over the course of about six weeks, that screen failure rates at their respective sites were trending higher than protocol assumptions anticipated. Each CRA mentioned it informally to their site contacts, each assumed it might be a local, site-specific issue, and none formally escalated it, because the organization's escalation process required building a documented case with statistical justification before raising anything to the program level, a bar that felt disproportionate for what each CRA individually perceived as a possibly minor, site-specific fluctuation.

By the time the pattern was finally recognized as portfolio-wide, during a routine quarterly review roughly ten weeks after the first CRA noticed it, the trial's enrollment timeline had already absorbed a meaningful, difficult-to-recover delay, and a root cause analysis traced the elevated screen failure rate to an eligibility criterion that had been interpreted inconsistently across sites from the start. A lower-cost first escalation rung, one that let any single CRA flag a pattern worth checking without first building a full statistical case, would very likely have surfaced the inconsistency within the first two or three weeks instead of ten.

Recommendations for PMO and Program Leaders

1. **Define escalation thresholds before you need them.** Set specific triggers in advance, at every level of the program, so raising an issue is a matter of meeting a pre-agreed threshold rather than an individual judgment call made under pressure.
2. **Build a genuinely low-cost first step.** Make the initial flag fast, informal, and blame-free, reserving the heavier documentation burden for issues that actually warrant it after an initial triage.
3. **Publicly protect people who escalate false alarms.** Make the absence of penalty visible and concrete, not just stated as policy, so the organization does not quietly train people to stay quiet.
4. **Commit to and honor response times at every level.** An escalation path only earns trust if the people using it see it consistently produce a timely response, not an occasional one.



5. **Monitor for both underuse and overuse.** Track whether the system is catching genuine early signals or drowning in noise, and recalibrate thresholds based on what you actually observe rather than what the original design assumed.
 6. **Treat near misses as data, not just full incidents.** Build a habit of reviewing escalated-but-resolved issues periodically for patterns, the same discipline healthcare safety systems are still working to build at scale.
-

Measuring Success: KPIs for Escalation Design

- **Near-miss-to-incident ratio:** the proportion of escalated issues that were caught before becoming a formal incident, tracked toward the higher ratio healthcare safety data suggests a well-functioning system should show.¹
 - **Escalation lead time:** the elapsed time between when an issue was first noticed by anyone and when it was formally escalated, tracked toward the days, not weeks, a well-calibrated first rung should enable.
 - **Response time compliance:** the percentage of escalations that received a response within the committed window at each level of the process.
 - **Escalation volume by rung:** the distribution of issues across the escalation ladder's levels, watching for either an empty first rung, suggesting people are not using it, or an overloaded top rung, suggesting lower levels are not absorbing what they should.
 - **Repeat-pattern detection rate:** the number of issues identified as a cross-program or cross-site pattern through escalation review, rather than discovered only after a formal incident had already occurred.
-

Conclusion

Every large program failure has a quieter history of small, missed signals behind it, and the gap between having an escalation process on paper and having one that actually functions is almost never about the org chart. It is about whether the people closest to a problem believe that raising it early is safe, fast, and likely to produce a response, or whether experience has taught them that silence is the lower-risk choice.

Applying disciplined best practices to a deliberate escalation design does not require new technology or a governance overhaul. It requires building a system around how people actually behave under uncertainty, low-cost first steps, defined thresholds, protected honesty, and reliable response times, rather than one that assumes rational, fearless reporting will simply happen on its own. Organizations that make that shift stop discovering their problems in a steering committee meeting and start catching them in the hallway conversation where someone first noticed something was off.

About OmniTek & Contact Information

OmniTek Consulting is a trusted partner for organizations seeking to enhance governance, operational agility, and decision-making. We specialize in modernizing business processes with a blend of human-centered design, technology expertise, and hands-on change management.



For PMO and program leaders whose escalation process exists on paper but rarely surfaces problems early, OmniTek applies proven best practices to build a practical escalation design model: pre-defined thresholds, a genuinely low-cost first step, and the response discipline that builds real trust in the system. Whether your organization is designing an escalation path for the first time or trying to understand why an existing one keeps missing problems until they are already serious, OmniTek can help you build the early-warning nervous system your programs actually need.

Contact us today to explore how OmniTek can support your transformation journey and drive lasting results.



McLean, VA | Serving
clients nationwide



info@omnitekconsulting.com



omnitekconsulting.com

[Click here to book a 15-minute call to see how OmniTek can help your team put these insights into practice.](#)

Endnotes

ⁱ Health Quality Institute (HQI), "A Window into Patient Safety: Underreporting of Near-Miss Events in CHPSOData," citing British Medical Journal research and 2023 AHRQ conference data, March 2024, available at <https://hqinstitute.org/a-window-into-patient-safety-underreporting-of-near-miss-events-in-chpsodata/>

ⁱⁱ WCG, 2026 Clinical Research Trends and Insights Report, as reported by Clinical Trial Vanguard, August 2026, available at <https://www.clinicaltrialvanguard.com/news/wcg-report-site-delays-and-phase-ii-terminations-rise-in-2025-clinical-trials/>

